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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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08/466,698 06/06/95 SANSONETTI

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EXAMINER

HM22/0426

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NAVARRO, A

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

04/26/99

**Please find below and/or attached an Office communication concerning this application or
proceeding.**

Commissioner of Patents and Trademarks

Office Action Summary

| | | |
|-------------------------------|------------------------|--|
| Application No. 08/464,698 | Applicant(s) | |
| Examiner Sansone et al. | Group Art Unit 1645 | |

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 4/15/99
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-8, 10 + 13-24 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-8, 10 + 13-24 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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DETAILED ACTION

Applicant's request for examination after final under 37 C.F.R. 1.129(a) and amendment filed on April 15, 1999 (Paper Number 31) has been received and entered. Consequently, claims 1-8, 10, and 13-24 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1-8, 10, and 13-24 under 35 U.S.C. 112, first paragraph, for reasons set forth in the Office Action mailed February 22, 1999 (Paper Number 29) is maintained.

As set forth previously, it is apparent that numerous modified *Shigella* are required to practice the claimed invention.

Applicant's are reasserting that the mutagenesis technique taught by the specification does not require knowledge of the nucleotide sequence of the target genes, does not require knowledge of regions of genes responsible for biological activity, and the number of nucleotides deleted or inserted is not critical to the practice of the claimed invention. Applicant's further assert that the method of Prentki and Krisch is not transposon mutagenesis, but an alternative to transposon mutagenesis involving an interposon. Applicant's arguments have been fully considered but are not found to be fully persuasive.

Applicant's arguments are not found to be fully persuasive in view of the teaching of Baudry *et al* (Submitted by Applicant's October 9, 1997, Paper Number 20, Exhibit 2) which set

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forth that “The available data indicate that the invasive ability of *S. flexerni* is a very complex phenomenon which involves many genes and a large array of polypeptides” and “Whether all these gene products are directly involved in the interaction with the cells, or whether a pool of polypeptides is necessary for transformation and/or correct positioning of a unique product is yet not known.” (See page 3411). In view that Baudry *et al* set forth that the invasive ability of *S. flexerni* involves many genes, and that it is unclear whether all these gene products are directly involved in the interaction with the cells, one of skill in the art would be forced into undue experimentation to determine which genes or combination of genes, and which modifications can be made to inactivate genes is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue, (Ex parte Forman 230 U.S.P.Q. 546 (Bd. Pat. App. & Int. 1986)). Furthermore, Applicant’s assert that claim 1, recites “other than only by inactivation by means of a transposon inserted into the genes” Applicant’s conclude that therefore, the quotation taken from Prentki and Krisch is not relevant to enablement of the claimed method. However, Applicant’s claims recite “other than by only a transposon” consequently transposon mutagenesis is encompassed within the scope of the claims if combined with another method of mutation, (e.g. pinpoint deletion), or even multiple transposons inserted within the genes. Therefore the teachings of Prentki *et al* are relevant to the scope of the claims, Prentki lists a number of obstacles which include, “Several difficulties, however, are associated with the use of transposons mutagens. First, some transposable elements exhibit a bias for the position of integration into the target molecule, either in a sequence specific manner..., or through

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a strong preference for A/T rich regions... Second, transcriptional activity into adjacent DNA has been reported..., sometimes complicating the phenotypic and genetic characterization of insertion mutants. Finally, once inserted into the target molecule, transposable elements have the capacity to generate DNA rearrangements such as deletions or inversions.” (See page 311) For the reasons set forth in Paper Number 29, as well as the above cited reasons this rejection is maintained.

2. The rejection of claims 13-14 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

Applicant's assert that “having read the specification and the preferred embodiments describing the *Shigella* strains SC501, SC504, SC505, and SC506, would have been apprised that invention concerned additional strains, above and beyond, the preferred embodiments.”

Applicant's further cite page 23 of the specification which recites “and it will be apparent that various modifications can be made in the method and vaccine described above without departing from the spirit and scope of the invention or sacrificing all of its material advantages, the embodiments described above being merely preferred embodiments.” Applicant's arguments have been fully considered but are not found to be fully persuasive.

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Applicant's arguments are not found to be fully persuasive in view of the claim language of claim 13 which recites "wherein said *Shigella* is other than those designated SC501, SC504, SC505, and SC506." While Applicant's set forth in the specification that "various modifications" can be made in the method and vaccine" this does not provide support for claiming an entire genus of the species "*Shigella*" based on the teaching of the preferred embodiments of individual species designated SC501, SC504, SC505, and SC506. For reasons of record in Paper Number 29, as well as the above cited reasons, this rejection is maintained.

Claim Objections

3. The objection of claim 17 because claim 17 does not end with a period at the end of the sentence is withdrawn in view of Applicant's amendment.

4. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.129(a) and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.129(a). Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the submission under 37 CFR 1.129(a). See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Dr. Anthony Caputa can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

Mark Navarro

April 24, 1999

Patricia A. Duffy
PATRICIA A. DUFFY
PRIMARY EXAMINER